Comparison between Citrus sinensis flowers and Mentha spicata leave essential oils inhalation on lung function and exercise performance among a group of athlete students

Submission date 10/06/2016	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 20/09/2016	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 20/10/2017	Condition category Other	Individual participant data

Plain English summary of protocol

Background and study aims

Recently, there has been a lot of interest in the effects of essential oils on athletic performance and health. Essential oils are natural oils which are taken from plants and other natural sources. They have been used for many years in alternative medicine, as they are thought to help improve the function of the mind and body. This study will look at oils from the Citrus sinensis (sweet orange) flower and Mentha spicata (spearmint) leaves to find out if they are able to improve lung function and athletic performance in healthy male athletes.

Who can participate?

Healthy male university students aged between 18 and 20 from the faculty of physical education at An-Najah National University in Nablus-Palestine.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group inhale M. spicata oil mixed with 2ml of normal saline (salt water) which has been turned into a vapor. Those in the second group inhale C. sinensis flower oil mixed with 2ml of normal saline (salt water) which has been turned into a vapor. Before and five minutes after inhalation, participants complete a breathing test using a spirometer (devise used for measuring the about of air breathed in and out) to test their lung function. In addition, before and after inhalation, participants run 1500 metres in a stadium to find out if inhaling the oil has improved their athletic performance.

What are the possible benefits and risks of participating? Participants may benefit from improved lung function and athletic performance as a result of taking part in the study. There are no notable risks involved with taking part in this study.

Where is the study run from? An-Najah National University (Palestinian Territory) When is the study starting and how long is it expected to run for? April 2016 to October 2016

Who is funding the study? Investigator initiated and funded (Palestinian Territory)

Who is the main contact? Dr Nidal Jaradat nidaljaradat@najah.edu

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 1/May/ 2016

Study information

Scientific Title

The effect of Inhalation of Citrus sinensis flowers and Mentha spicata leave essential oils on lung function and exercise performance: a quasi-experimental uncontrolled before-and-after study

Study objectives

The aim of this study is to compare the effects between the Citrus sinensis flower and Mentha spicata leaves essential oils inhalation among a group of athlete male students on their lung functions

Ethics approval required

Old ethics approval format

Ethics approval(s) Institutional Review Board (IRB) at An Najah National University, 03/05/2016, ref: 1/May/2016

Study design Single-centre randomised parallel trial

Primary study design Interventional

Secondary study design Randomised parallel trial

Study setting(s) Other

Study type(s) Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Exercise performance and lung function

Interventions

Twenty male university students from the faculty of physical education at An-Najah National University in Nablus-Palestine will be randomly assigned into two different groups. The study is single blind participant level.

Group 1: Participants will nebulize with M. spicata oil (0.02ml/kg of body mass of oil) mixed with 2ml of normal saline.

Group 2: Participants will nebulize with C. sinensis flower oil (0.02ml/kg of body mass of oil) mixed with 2ml of normal saline.

Participants in both groups completed a 1500m run test in a stadium race before and after inhalation of the oils, they inhaled the oils 5 minutes before running. Lung function tests are undertaken using a spirometer before and after inhalation.

Intervention Type

Other

Primary outcome measure

Lung function is measured using spirometry before and 5 minutes after inhalation of volatile oil.

Secondary outcome measures

Athletic performance is measured using a 1500 meter run test before and after inhalation of volatile oil.

Overall study start date 01/04/2016

Completion date

01/10/2016

Eligibility

Key inclusion criteria

 Healthy
 Male university students from the faculty of physical education at An-Najah National University in Nablus-Palestine
 Aged between 18-20 years

Participant type(s) Healthy volunteer

Age group Adult

Lower age limit 18 Years

Upper age limit 20 Years

Sex Male

Target number of participants 20

Key exclusion criteria Suffering from any disease

Date of first enrolment 22/06/2016

Date of final enrolment 22/07/2016

Locations

Countries of recruitment

Study participating centre An-Najah National University West Bank Nablus Palestine, State of 00970

Sponsor information

Organisation An-Najah National University

Sponsor details Department of Pharmacy Palestine-West Bank An-Najah National University Nablus Palestine, State of 00970 +970 (0)9 2345113 info@najah.edu

Sponsor type University/education

Website https://www.najah.edu/ar/

ROR https://ror.org/0046mja08

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date

01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	22/09/2016		Yes	No